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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,734	06/03/2002	Anthony Michael Heagerty	078986/0207	8287

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EXAMINER	
GRUN, JAMES LESLIE	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,734	HEAGERTY, ANTHONY MICHAEL	
	Examiner	Art Unit	
	James L Grun	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 17-31 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 17-31 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 05/01/2002.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Claims 17-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's disclosure is based upon mere speculation that cardiotrophin-1 levels would be detectable in human bodily fluids and upon mere speculation that the levels thereof would have any correlations to cardiac hypertrophy. The messenger RNA for the protein was known to be expressed in a variety of human tissues (see, e.g., Pennica et al., 1996, Cytokine 8: 183), thus specificity of any levels detected in an unspecified or generic body fluid from an unselected patient population as indicative of cardiac involvement in a given patient would seem entirely

unknown and unpredictable absent further experimentation. Indeed, at the time the application was filed, it would seem that there was no predictability even that levels of cardiotrophin-1 protein were secreted and detectable in human blood, serum, or plasma, let alone the other body fluids suggested by applicant. Applicant provides no description or guidance to an assay, particularly to a specific functional antibody reagent, which specifically determines cardiotrophin-1, does not cross-react to an undesirable degree with related molecules in the IL-6 family, and is not interfered with by blood, serum, or plasma components. Indeed, Ng et al. (Clin. Sci. 102: 411, 2002) teach that extraction of samples was required for competitive assays for cardiotrophin-1 prior to the publication date of the reference. Applicant's specification provides a suggestion to experiment further to determine if the levels of the protein are detectable in the suggested body fluid samples and if those levels, if detectable, correlate with cardiac disease. Such experimentation may be "obvious to try", but such an invitation to experiment does not provide an indication that applicant had possession of the invention as claimed at the time the application was filed and does not provide an enabling disclosure. In this regard there is also no predictable correlation between an improved condition after treatment and declining levels of protein as Ishikawa et al. (1999) could detect no change in mRNA expression levels after a treatment that prevented cardiac hypertrophy in an animal model. Moreover, it would seem entirely unknown and unpredictable that nucleic acids, or changing levels thereof, would be detectable in body fluid samples as is claimed. Applicant provides no adequate description or guidance for appropriate samples for nucleic acid determinations unless applicant intends that one obtain tissue samples from a human patient's heart, as done for rats in Ishikawa et al. (1999), to diagnose a predisposition to heart hypertrophy by detection of nucleic acid

expression. Applicant does not provide sufficient written description or guidance that would assure one of the ability, particularly at the time the application was filed, to practice the invention as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-31 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 17 and claims dependent thereupon, "the level" lacks antecedent basis. The interrelationships of the components of the method are not clear, e.g. it is not clear: in who or in what diagnosis is being made; or, what the standard of comparison for "elevated" encompasses for other than claims 18 or 19.

In claims 20 and 21, "the initiation or onset" lacks antecedent basis and the relationship of these to "diagnosing or detecting a predisposition" are not clear.

In claims 24 and 25, it is not clear what components or conditions are required to arrange detection of protein or fragments, thus the metes and bounds of the invention for which applicant desires coverage cannot be determined.

In claims 26 and 27, it is not clear what components or conditions are required to arrange detection of nucleic acid or fragments, thus the metes and bounds of the invention for which applicant desires coverage cannot be determined.

In claims 28 and 29, it is not clear what additional steps applicant is intending to encompass as no further steps are positively recited.

Claim 30 provides for the use of a method, but, since the claim does not set forth any additional steps involved in the method/process, it is unclear what method/ process applicant is intending to encompass. The intended use of the method does not further limit the method of claim 17. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

In claim 31, "the efficacy" and "the level" lack antecedent basis. The interrelationships of the components of the method are not clear, e.g. it is not clear: in who or in what efficacy is being determined; or, what the standard of comparison for "reduced" encompasses.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 17, 18, 20, 21, 23-25, 30, and 31 are rejected under 35 U.S.C. § 102(a) as being clearly anticipated by Talwar et al. (Biochem. Biophys. Res. Comm. 261: 567, Aug. 11, 1999.

Talwar et al. teach an immunoassay for determination of cardiotrophin-1 plasma levels in normal humans and humans with heart failure related to eccentric hypertrophy or pressure overload (see e.g., pages 568, 570, and 571).

Applicant's claims have not been accorded the benefit of the filing dates of the priority documents for the same reasons set forth supra under 35 U.S.C. § 112, first paragraph.

The prior art or art made of record and not relied upon is considered pertinent to applicant's disclosure.

Pennica et al. (Cytokine 8: 183, 1996) teach human cardiotrophin-1 and its tissue localization.

Baker et al. (U.S. Pat. No. 5,627,073) disclose and claim antibodies specific for mouse and human cardiotrophin-1 and teach the use of the antibodies for detection assays (see e.g. cols. 3-4, 12-14, 35-36, and 46-55).

Baker et al. (U.S. Pat. No. 5,624,806) disclose and antibodies specific for mouse and human cardiotrophin-1 and teach and claim the use of the antibodies for detection assays (see e.g. cols. 3-4, 12-14, 35-36, and 46-55).

Ng et al. (Clin. Sci. 102: 411, 2002) teach a non-competitive assay for human cardiotrophin-1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone numbers for official facsimile transmitted communications to TC 1600, Group 1640, are (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

James L. Grun, Ph.D.
September 27, 2004

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641
9/28/04